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TO: U.S. Patent and Trademark Office **FROM:** Guy V. Tucker, Reg. No. 45,302
Mail Stop Appeal Brief - Patents

EXAMINER: Shumaya B. ALI **PHONE NUMBER:** 650.620.5501
Group Art Unit: 3771

FAX NUMBER: 571-273-8300 **FAX NUMBER:** 650.620.6395

PHONE NUMBER: **DATE:** June 8, 2007

RE: U.S. Serial No.: 10/729,847 **TOTAL NO. OF PAGES INCLUDING COVER:** 13
Docket No.: 0138.00

The following documents are submitted:

1. Transmittal Form PTO/SB/21 - 1 page
2. Appeal Brief - 11 pages

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PTO/SB/21 (04-07)

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Total Number of Pages in This Submission

13

Application Number

10/729,847

Filing Date

December 5, 2003

First Named Inventor

William Alston

Art Unit

3771

Examiner Name

Ali, Shumaya B.

Attorney Docket Number

0138.00

ENCLOSURES (Check all that apply)

- ☐ Fee Transmittal Form
- ☐ Fee Attached
- ☐ Amendment/Reply
- ☐ After Final
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/Incomplete Application
- ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53

- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation
- ☐ Change of Correspondence Address
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- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
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- ☐ After Allowance Communication to TC
- ☒ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) (please identify below):

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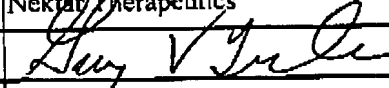
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name

Nektar Therapeutics

Signature



Printed name

Guy V. Tucker

Date

June 8, 2007

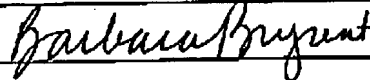
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Barbara Bryant

Date

06/08/2007

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I hereby certify that the following papers are being facsimile transmitted to Mail Stop Appeal Brief-Patents at the Patent and Trademark Office at facsimile number 571-273-8300 on the date indicated below.

Signed: _____

Barbara Bryant

Dated: _____

June 8, 2007

PATENT

.....

In the United States Patent and Trademark Office

.....

Applicant: ALSTON, William

Applicant's Ref: 0138.00

Application No: 10/729,847

Filed: December 5, 2003

Title: AEROSOLIZATION APPARATUS WITH ROTATING CAPSULE

Examiner: Ali, Shumaya 3

Group Art Unit: 3771

Confirmation No.: 8316

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action of October 11, 2006 the Applicant of the above-referenced patent application (hereinafter Appellant) hereby appeals to the Board of Patent Appeals and Interferences.

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PATENTApplicati n No. 10/729,847
Attorney Docket No.: 0138.00**(1) Real Party in Interest**

The real party in interest of the present application is Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.), having a place of business at 150 Industrial Road; San Carlos, California 94707.

(2) Related Appeals and Interferences

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) Status of Claims

Claims 1-20 are presently pending in the case. Claims 1-20 have been finally rejected. The rejection of each of claims 1-20 is hereby appealed.

(4) Status of Amendments

No amendments after Final Rejection have been filed. Accordingly, all amendments made during prosecution of the case have been entered.

(5) Summary of the Claimed Subject Matter

As discussed on page 5 line 20 through page 7 line 9 and shown in Figures 1A-1E, for example, an aerosolization apparatus comprises a body defining an inlet opening (115), an outlet opening (120, 145), and an aerosolization chamber (110) between the inlet opening and the outlet opening. The aerosolization chamber (110) is adapted to receive an elongated receptacle (125) containing a pharmaceutical formulation. The aerosolization chamber (110) is configured so that the elongated receptacle (125) rotates end-over-end (175, see Figure 1E) about an axis substantially orthogonal to an axis (170) passing through the outlet opening (120, 145) when air or gas flows through the body. Stated another way, the rotation is about an axis substantially orthogonal to the inhalation direction (170) when air or gas flows through the body.

(6) Grounds of Rejection to be Reviewed on Appeal

Appellant requests review of the Examiner's following grounds of rejection:

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Claims 4 and 14, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7, 10-17 and 20, rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,249,526 to Dean et al (hereinafter Dean et al).

Claims 8 and 18 rejected under 35 USC 103(a) as being unpatentable over Dean et al.

Claims 9 and 19, rejected under 35 USC 103(a) as being unpatentable over Dean et al in view of U.S. Patent 5,614,217 to Chiprich et al (hereinafter Chiprich et al).

(7) Argument

Appellant believes each of claims 1-20 are improperly rejected and are therefore allowable for the following reasons.

The rejection of claims 4 and 14 under 35 U.S.C. 112, second paragraph is improper

Claims 4 and 14 meet the requirements of 35 U.S.C. 112, second paragraph. Claim 4, for example, recites an "aerosolization apparatus according to claim 1 further comprising the receptacle." The "receptacle" is only functionally recited in claim 1. Dependent claim 4 includes all of the limitations of claim 1 and also positively recites the receptacle. The Examiner's contention that the "meets and bounds of claimed limitation cannot be determined" is not understood or proper. Claim 14 is similarly compliant with 35 U.S.C. 112 second paragraph.

The rejection of independent claim 1 under 35 U.S.C. 102(b) is improper

Independent claim 1, for example, is not anticipated by Dean et al. Claim 1 is to an aerosolization apparatus comprising a body defining an inlet opening, an outlet opening, and an aerosolization chamber between the inlet opening and the outlet opening, wherein the

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aerosolization chamber is adapted to receive an elongated receptacle containing a pharmaceutical formulation and wherein the elongated receptacle rotates end-over-end about an axis substantially orthogonal to an axis passing through the outlet opening when air or gas flows through the body. Dean et al does not satisfy the requirements of Appellant's claim 1. As can be seen in Figures 1 and 2 of Dean et al, a receptacle (24) in the aerosolization chamber (15) of Dean et al rotates about an axis that is parallel to the axes passing through the outlet opening (5) of Dean et al. Thus, Dean et al does not disclose a chamber wherein a receptacle would rotate about an axis that is *orthogonal* to the axis of the outlet opening. Accordingly, Dean et al does not anticipate claim 1.

The Examiner's position regarding this language is unclear. According to page 3 of the Final Office Action, the Examiner states that the "2-fold axis of symmetry reads on end-over-end, see col. 4 lines 32-38, figs.3 and 4." While unclear, it is assumed the Examiner is of the position that an axis passing horizontally on the page showing Figure 1 of Dean et al could be taken to be the claimed "axis passing through the opening" of Appellant's claim 1. Such an interpretation would be a distortion of terms beyond that which one of ordinary skill in the art would be inclined to make. First, the language of the claim states that the axis passes "through" the opening. The Examiner's alleged axis does not pass *through* the opening in like manner or as one of ordinary skill would interpret the expression. Second, the Appellant has sufficiently defined in the specification what was meant by the "axis passing through the opening" (see page 7 lines 1-9, for example). Furthermore, it should be noted that aerosolization devices where a receptacle rotates in the manner of Dean et al were acknowledged by the Appellant in the Appellant's specification (see, for example, page 6 line 18). It was clearly the Appellant's intention to distinguish the present claims over such devices by defining the manner of receptacle rotation. An end-over-end rotation of the type invented is not present in the prior art and it is this rotational manner that is being claimed.

Claims 2-9 depend from claim 1 and are also not anticipated by Dean et al.

The rejection of independent claim 10 under 35 U.S.C. 102(b) is improper

Independent claim 10 is similar to Appellant's independent claim 1, with the exception that "axis passing through the opening" is replaced with "axis parallel to an inhalation direction." This axis recitation is defined by Appellant in the specification and in Figure 1E.

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The receptacle in Dean et al clearly does not rotate about such an axis and therefore does not anticipate claim 10.

Claims 11-20 depend from claim 10 and are also not anticipated by Dean et al.

The rejection of claims 8, 9, 18, and 19 under 35 U.S.C. 103(a) is improper

Dean et al does not render claims 8, 9, 18, and 19 unpatentable either singly or in combination with Chiprich et al. Claims 8 and 9 depend from claim 1 and claims 18 and 19 depend from claim 10. Each of claims 1 and 10 recite a chamber providing a manner of receptacle rotation that is not present in Dean et al, as discussed above. The Examiner does not suggest that it would have been obvious to modify the rotational arrangement of Dean et al (nor would it be). Accordingly, the limitations of independent claims 1 and 10 are not met by any modification proposed by the Examiner and there is thus no creation of a prima facie case of obviousness. Chiprich et al also fails to disclose or suggest the necessary rotational arrangement and is of no moment in this consideration. Accordingly, claims 8, 9, 18, and 19 are not rendered unpatentable by Dean et al or by Dean et al in combination with Chiprich et al.

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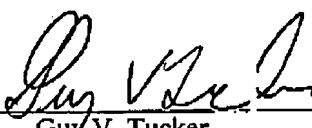
PATENTApplication No. 10/729,847
Attorney Docket No.: 0138.00**Conclusion**

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

In the event it is determined that any fee is due, the Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-0348.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

NEKTAR THERAPEUTICS
(formerly INHALE THERAPEUTIC
SYSTEMS)Dated: 08 JUN 2007By: 
Guy V. Tucker
Reg. No. 45,302

Please send all correspondence to:
Guy Tucker
Nektar Therapeutics
(formerly Inhale Therapeutic Systems, Inc.)
150 Industrial Road
San Carlos, CA 94070
Phone: (650) 620-5501
Fax: (650) 631-3125

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(8) Claims Appendix

1. An aerosolization apparatus comprising:
a body defining an inlet opening, an outlet opening, and an aerosolization chamber between the inlet opening and the outlet opening,
wherein the aerosolization chamber is adapted to receive an elongated receptacle containing a pharmaceutical formulation and wherein the elongated receptacle rotates end-over-end about an axis substantially orthogonal to an axis passing through the outlet opening when air or gas flows through the body.
2. An aerosolization apparatus according to claim 1 further comprising an opening mechanism for creating an opening in the receptacle.
3. An aerosolization apparatus according to claim 2 wherein the opening mechanism comprises a sharpened tip moveable within the aerosolization chamber.
4. An aerosolization apparatus according to claim 1 further comprising the receptacle.
5. An aerosolization apparatus according to claim 4 wherein the receptacle comprises a capsule.
6. An aerosolization apparatus according to claim 5 wherein the capsule comprises a wall comprising one or more of gelatin, hydroxypropyl methylcellulose, polyethyleneglycol-compounded hydroxypropyl methylcellulose, hydroxypropylcellulose, and agar.
7. An aerosolization apparatus according to claim 5 wherein the receptacle contains a powder pharmaceutical formulation.
8. An aerosolization apparatus according to claim 7 wherein the powder pharmaceutical formulation comprises particles having a mass median diameter less than 10 μm .

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9. An aerosolization apparatus according to claim 7 wherein the powder pharmaceutical formulation has a moisture content below 5% by weight.
10. An aerosolization apparatus for delivering an aerosolized pharmaceutical formulation to a user's respiratory tract, the apparatus comprising:
a body defining an inlet opening, an outlet opening, and an aerosolization chamber between the inlet opening and the outlet opening,
wherein the aerosolization chamber is adapted to receive an elongated receptacle containing a pharmaceutical formulation and wherein the elongated receptacle rotates end-over-end about an axis substantially orthogonal to an axis parallel to an inhalation direction when the user inhales to cause air or gas to pass through the body.
11. An aerosolization apparatus according to claim 10 wherein the inhalation direction is a direction coincident with an axis passing through a mouthpiece of the apparatus.
12. An aerosolization apparatus according to claim 10 further comprising an opening mechanism for creating an opening in the receptacle.
13. An aerosolization apparatus according to claim 12 wherein the opening mechanism comprises a sharpened tip moveable within the aerosolization chamber.
14. An aerosolization apparatus according to claim 10 further comprising the receptacle.
15. An aerosolization apparatus according to claim 14 wherein the receptacle comprises a capsule.
16. An aerosolization apparatus according to claim 15 wherein the capsule comprises a wall comprising one or more of gelatin, hydroxypropyl methylcellulose, polyethyleneglycol-compounded hydroxypropyl methylcellulose, hydroxypropylcellulose, and agar.
17. An aerosolization apparatus according to claim 15 wherein the receptacle contains a powder pharmaceutical formulation.

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18. An aerosolization apparatus according to claim 17 wherein the powder pharmaceutical formulation comprises particles having a mass median diameter less than 10 μm .

19. An aerosolization apparatus according to claim 17 wherein the powder pharmaceutical formulation has a moisture content below 5% by weight.

20. An aerosolization apparatus according to claim 10 wherein the inlet opening is shaped to cause a swirling air or gas flow through the chamber.

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(9) Evidence Appendix

none

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(10) Related Proceedings Appendix

none